

REMARKS

Review and reconsideration of the non-final Office Action mailed February 26, 2010 (hereinafter "Office Action"), is respectfully requested in view of the following remarks. This Amendment is accompanied by credit card authorization to charge the \$65 small entity fee for a one-month extension of time. Although no additional fees are believed due, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 14-1437.

At the time of the Office Action, claims 1, 2, 4, 7-9 and 14-16 were pending, with claims 1-4, 6-9, and 14-16 being drawn to an elected invention. In the Office Action, all claims were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,536,405 by Nara *et al.* (hereafter "Nara") in view of U.S. Patent No. 5,851,517 by Mougin *et al.* (hereafter "Mougin"), U.S. Patent No. 5,580,550 by Gough *et al.* (hereafter "Gough"), and U.S. Patent No. 6,503,495 by Alwattari (hereinafter "Alwattari"). Applicants respectfully submit that the new references add nothing that would change the conclusion that the unexpected results discussed herein (and in the previous responses and Declarations) overcome any case of obviousness, if one were in fact established (which Applicants dispute).

Prior to addressing the cited art, Applicants wish to review the claimed cosmetic composition as set forth in independent claim 1, which recites:

1. (Currently Amended) A cosmetic composition, suitable for application to facial skin, lips and eyelashes, consisting of:
from 2 to 25% of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range;
from 0.05 to 20% of disteardimonium hectorite;
from 1.1 to 90 % of isododecane;
the balance comprising conventional cosmetic excipients, colourants and additives, all percentages being by weight of the final composition, wherein said cosmetic composition is a substantially anhydrous composition.

The claimed cosmetic composition suitable for application to facial skin, lips and eyelashes is a substantially anhydrous composition that consists of 2 to 25 wt-% *polyisoprene*

produced by a comminuting and depolymerizing process, 0.05 to 20 wt-% disteardimonium hectorite, 1.1 to 90 wt-% isodecane, and conventional cosmetic excipients, colourants and additives. The polyisoprene is produced by step a), which comprises comminuting, *i.e.*, crushing or grinding, a solid polyisoprene with a molecular weight between 100,000 and 4,000,000, and step b), which comprises depolymerising the comminuted solid isoprene of step a).

As has been thoroughly demonstrated previously, the particles produced by a claimed comminuting process have a substantially rougher surface morphology and more irregular shape than the spherical particles produced by conventional emulsion polymerization techniques. It is believed that, when combined with the other claimed ingredients, the rough surface morphology and irregular shape of the comminuted polyisoprene particles contributes to the properties of the claimed cosmetic compositions, which can be applied to the facial skin, the lips and the eyelashes to produce an unexpectedly stable, homogeneous, and long-lasting film. *None of the cited references, whether existing or new, disclose or suggest the claims polyisoprene produced by a comminuting and depolymerizing process or the unexpected results produced when the claimed polyisoprene is combined with the other claimed ingredients in the claimed amounts.* Furthermore, because the results produced are unexpectedly superior and different in kind from what the prior art discloses, any assertion of optimization is improper.

Cosmetic products for make-up of face, lips, eyelashes, etc., often suffer from the drawback that, when they come into contact with fingers or clothing, they tend to smudge or soil these surface. In addition, in some cases the make-up can also appear to be not homogeneous.

In view of these existing issues, the technical problem that underlies the present invention is that of providing a cosmetic composition which is stable, has high film-forming property and provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes (present application, page 1, lines 8-15 and on page 2, lines 15-18) and therefore does not smudge the surface to which it come into contact such as, for example, fingers or clothing (present application, on page 1, lines 8-15).

Applicant has unexpectedly discovered that problem can be solved by the claimed substantially anhydrous cosmetic composition endowed with the combinative effect of the presence of the *three claimed ingredients in the claimed amounts*, *i.e.*, 1) 2 to 25% of

polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) 0.05 to 20% *disteardimonium hectorite*, and 3) 2.2 to 90% *isododecane*.

The advantageous effects of the combination of the above three elements have been extensively demonstrated by means of experimental data shown in the First Maio Declaration submitted March 16, 2009 (hereinafter "First Maio Declaration"), which the Examiner found persuasive in order to overcome the obviousness rejection in view of the previously cited prior art.

The first new cited prior art is Nara, which relates to a make-up cosmetic composition having good oil resistance, water resistance and adhesion, which contains at least one of (a) an organosoluble or a water- and organo-soluble ethyl hydroxyethyl cellulose and (b) and aromatic hydrocarbon resin having a softening point of at least 120°C. (Nara, Abstract).

Among the three claimed ingredients of the present cosmetic composition, Nara only mentions polyisoprene, which is embedded as penultimate and ultimate compounds in a long list of 76 suitable resins. (Nara, Table 2). In particular, Nara discloses the polyisoprenes are that sold by trade name Escorez 1071U and Escorez 1103U. (Nara, Table 2). Attached hereto as Exhibit A is product information on Escorez. As it is shown in Exhibit A, Escorez are resinous and glassy polymers or copolymers of the cyclopentene. On the contrary, the polyisoprene of the present invention is an elastomeric and rubbery polymer with a linear structure and not with a cyclic structure as the Escorezs disclosed in Nara. Also, as acknowledged in the Office Action, Nara fails to teach the molecular weight of the polyisoprene used.

Moreover, it is to be noted that the resins used in Nara's composition are aromatic type resins which are known by persons of skill in the art to have a very critic toxicological profile, although in Nara's patent this was denied. (Nara, col. 8, lines 44-48).

As such, Nara does not change the fact that none of the cited references disclose or suggest the claimed combination of ingredients including *2 to 25% of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid*

polyisoprene of step a) to a molecular weight within the above range. Additionally, as acknowledged in the Office Action, Nara fails to teach the components of disteardimonium hectorite and isododecane.

The second new cited prior art is Mougin, which relates to the use of a dispersion of surface-stabilized polymer particles in a non-aqueous medium, in a cosmetic, hygiene or pharmaceutical composition. (Mougin, Abstract).

Among the above cited three claimed ingredients of the present cosmetic composition, Mougin only mentions isododecane (Mougin, col. 3, line 49), embedded in a long list of other suitable oils. (Mougin, col. 3, lines 37-62). Thus, there is no motivation to specifically select isododecane from that list to produce the unexpected results of the claimed composition. Mougin also clearly fails to teach the components of polyisoprene and disteardimonium hectorite. Therefore, Mougin does not correct the deficiencies from Nara outlined above.

Moreover, Mougin clearly relates to a cosmetic composition in the form of an emulsion, i.e. a dispersion of a polymer in particles stabilized by emulsifying agents or ionic system in the polymer. (See, e.g., Mougin, col. 2, lines 30-33). On the contrary, ***the present cosmetic composition is a homogeneous solution of the polyisoprene in a perfectly compatible solvent.*** Therefore, Mougin does not correct the deficiencies from Nara outlined above.

As discussed in the previous response, Gough relates to a cosmetic composition comprising an emulsion, preferably an aqueous emulsion, including at least one cosmetic resin material, e.g., a hydrocarbon resin such as polyisobutylene, made by direct emulsification of the resin without a solvent or carrier thereof. The direct emulsification may be achieved by a special mixing regime, with particular emulsifiers. The absence of solvent or carrier for the resin material would avoid product thinning and gives several manufacturing and processing advantages. (Gough, Abstract). In particular, the Gough's cosmetic composition is a hair care composition such as a shampoo, wherein the hydrocarbon resin is preferably a per-alk(en)yl hydrocarbon material with a weight average molecular weight between 150 and 10,000,000. (Gough, Col. 3, lines 26-28).

Among the above cited three claimed ingredients of the present cosmetic composition, Gough only cites polyisoprene in the form of natural rubber (cis-1,4-polyisoprene) embedded in a

long list of possible hydrocarbon resins (Gough, col. 3, lines 45-54). Thus, there is no motivation to specifically select polyisoprene from that list to produce the unexpected results of the claimed composition.

Moreover, it is to be noted that cosmetic composition of Gough is not anhydrous. In fact, the shampoo B comprises polyisobutylene and water (Gough, col. 9, lines 30-40). Therefore, Gough does not correct the deficiencies from Nara or Mougin outlined above.

As discussed in the previous response, Alwattari relates to oil-in-water mascara compositions comprising water-insoluble polymeric materials in the form of an aqueous emulsion, water soluble, film-forming polymers and organophilic clays. (See Alwattari).

Among the above cited three claimed ingredients of the present cosmetic composition, Alwattari only cites Bentone 38 (*i.e.*, disteardimonium hectorite) embed in a long list of possible organophilic clays (Alwattari, col. 5, lines 61-67 and col. 6, lines 1-19). Thus, there is no motivation to specifically select disteardimonium hectorite from that list in order to produce the unexpected results of the claimed composition.

In view of the foregoing, Applicants respectfully submit that a skilled person faced with the problem of the present invention, by reading the cited prior arts Nara, Mougin, Gough, and Alwattari would not find any hint or suggestion to select: 1) a polyisoprene obtainable as described steps of *a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range*; 2) disteardimonium hectorite and 3) isododecane as three specific essential elements of an anhydrous cosmetic composition capable of solving the above problem. In the instant application, the claimed cosmetic composition unexpectedly demonstrates superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. The specific mixture of ingredients can only be produced by taking the cited references and (i) assuming polyisoprene particles produced by comminuting a solid polyisoprene and depolymerizing the polyisoprene is the same as the polyisoprene sold under the trade names Escorez 1071U and Escorez 1103U (which is an erroneous assumption), and (ii) assuming that a person of skill in the art would (a) select disteardimonium hectorite from a long list of potential options, (b) select isododecane from a long list of potential options, (c)

include these ingredients in the claimed amounts, and (d) decide to make a homogeneous solubilization, despite the fact the references specifically teach emulsions. Furthermore, *the rejection fails to identify any reference disclosing the claimed isoprene particles produced by a combination of comminuting and depolymerizing, much less the use of such particles in a cosmetic composition.* Thus, it is Applicants' position that the cited references fail to establish a *prima facie* case of obviousness.

Regardless of whether a *prima facie* case of obviousness has been established, Applicants note that the Federal Circuit has held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *See In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987); MPEP §§ 716.02(a).II. & 2145.

Applicants respectfully submit that the combination of the cited references does not render the claimed cosmetic composition obvious because (1) the rejection fails to disclose each element of the claims, including the claimed isoprene particles produced by a comminuting and depolymerizing process, (2) the rejection relies on the assumption that several ingredients are interchangeable or equivalent when, in fact, they are not, and (3) because the claimed combination of ingredients produces unexpected results that are neither disclosed nor suggested by the cited references.

In order to demonstrate the unexpected results obtained by the claimed cosmetic composition, Applicants submitted the Declaration Under 37 C.F.R. §1.132 by co-inventor Giuseppe Maio (hereinafter "First Maio Declaration"). As discussed in the previous response and as explained by Mr. Maio:

During my experiments, I have surprising[ly] found that the combination of 1) a polyisoprene (from 2 to 25% (w/w)) obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite (0.05 to 20% (w/w)) and 3) isododecane (from 1.1 to 90% (w/w)), the balance comprising conventional cosmetic excipients, colorants and additives, is critical in order to achieve an anhydrous cosmetic composition which is stable and provides for the deposition of a homogeneous, long lasting film onto the facial skin, the lips

and the eyelashes.

First Maio Declaration, Section 4.

Mr. Maio conducted extensive experimentation in order to arrive at the claimed cosmetic composition. From all of the compositions tested in these experiments, Mr. Maio has selected the following three in order to demonstrate the dramatic and unexpected improvements produced using the claimed ingredients. While additional details of compositions REM 513.32, REM 513.33, and REM 5123.34 can be found in the First Maio Declaration, Section 4, a summary of these compositions is found below:

	REM 513.32	REM 513.33	REM 513.34
Polyisoprene	10.0 wt-% comminuted KRATON IR 310	10.0 wt-% comminuted KRATON IR 310	15.0 wt-% polyisoprene <u>latex</u> (KRATON IR401B)
Disteardimonium hectorite (BENTONE 38V)	6.0 wt-%	0.0 wt-%	6.0 wt-%
Isododecane	79.0 wt-%	85.0 wt-%	73.5 wt-%
Colourants	5 wt-%	5.0 wt-%	5 wt-%

The properties of these compositions were as follows:

REM 513.32

Aspect: Creamy fluid stable product endowed with high long lasting film properties.
Drying time after application: 3 minutes

REM 513.33

Aspect: Liquid unstable product, after 2 hours from its preparation the product shows an evident color phase separation and thus making the product not applicable.
Drying time after forced application; 6 minutes

RE 513.34

Aspect: Doughy unstable product, visually unhomogeneous and thus making the product not applicable.
Drying time after forced application: 10 minutes

In order to evaluate the aspect and the drying time, the unstable comparative products, *i.e.*, REM 513.33 and REM 513.34, have been made homogeneous. *See* First Maio Declaration,

Section 4. Each of the compositions was evaluated using a transferability resistance assay and a saliva resistance assay.

The results of the Transferability Resistance Assay after 10 wipes were as follows:

REM 513.32	REM 513.33	REM 513.34
No transfer	Very poor transfer	Poor transfer

As noted by Mr. Maio:

[T]he films of the comparable product REM 513.34 deposited on the paper were visually unhomogeneous. As far as the comparable product REM 513.34 is concerned, it showed very evident colour streaks and its deposited film was easily removed by means of a finger wipe.

First Maio Declaration, Section 4.

The results of the Saliva Resistance Assay after 5 wipes, were as follows:

REM 513.32	REM 513.33	REM 513.34
Clean tampon, no colour transfer	Slightly colour dirty tampon, slight ring	Slightly colour dirty tampon, slight ring

Maio Declaration, Section 4.

In evaluating the experimental data, Mr. Maio explains:

From the above experimental data, it is evident that the combinative effect of the presence of the three specific components selected, *i.e.*, 1) the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite and 3) isododecane (REM 513.32) is essential in order to achieve a stable anhydrous cosmetic composition endowed with high film-forming property, which is easy to use and stable over a medium-long term and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown from the above data, only the invention product: (REM 513.32) is endowed with a homogeneous creamy fluid aspect, has good film-forming property and a short drying time after application which makes it easy to use.

Furthermore, from the data shown above, it is also evident that the invention product (REM 513.32) is also a stable product.

On the contrary, all the comparative products (REM 513.33 and REM 513.34) are unstable and with an unhomogeneous aspect and therefore unsuitable for the preparation of a cosmetic composition for application to facial skin, lips and eyelashes.

First Maio Declaration, Section 5.

With this testing as background, Applicants have demonstrated that the claimed cosmetic composition is not disclosed or suggested by any combination of the cited art and that the claimed cosmetic composition, including the claimed ingredients in the claimed amounts, exhibits unexpected properties that are not disclosed or suggested by the cited references.

In *In re Chupp*, the claims at issue were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average herbicidal results for other crops. See *id.*, at 644. The prior art was a homolog of the claimed compound that differed from the claimed compound by a single methylene group (C=C), and was disclosed as being a selective herbicide for crops generally. Thus, the difference between the claimed compound and the prior art was a single methylene group and an unexpected improvement in herbicidal efficacy that was limited to two crops.

The Court noted that the claimed compound's "superior activity in corn and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound was similar to the prior art and provided average selective herbicidal activity for many crops and poor herbicidal activity for others. *The Federal Circuit concluded that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a prima facie case of obviousness.* See *id.*, at 646.

Finally, the case law clearly establishes that, "Although evidence of unexpected results must compare the claimed invention with the closest prior art, ***applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art.*** *In re*

Geiger, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) (Evidence rebutted *prima facie* case by comparing claimed invention with the most relevant prior art. Note that the majority held the Office failed to establish a *prima facie* case of obviousness.); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966) (Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 "would be requiring comparison of the results of the invention with the results of the invention." 357 F.2d at 422, 148 USPQ at 714.).” MPEP 716.02(e). Thus, the newly cited references do not change the result that the evidence of unexpected results demonstrates the importance of all three ingredients, including the element that the polyisoprene is produced by the steps of *a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range*,

The Federal Circuit nicely summarizes cases in this line by stating "*Obviousness cannot be predicated on what is not known at the time an invention is made.*" *In re Rijckaert*, 9 F.2d 1531, 1534 (Fed. Cir. 1993). In the instant case, it simply was not known that the claimed combination of the ingredients, in the claimed amounts, would unexpectedly exhibit superior properties by depositing a homogenous, long-lasting film on the facial skin, the lips and the eyelashes. Accordingly, Applicants respectfully submit that the evidence of unexpected results submitted herewith is sufficient to overcome a *prima facie* case of obviousness, if one has been established (which Applicants would argue it has not). In view of the foregoing, Applicants respectfully request that the rejection based on the combination of Nara, Mougin, Gough and Alwattari.

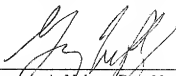
Conclusion

For at least the reasons set forth above, the independent claim is believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicants invite the Examiner to call the undersigned, Greg Lefkowitz (direct line 561-838-5229 x228), if it is

believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,
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Date: June 25, 2010



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